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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,460	02/15/2002	Bettina Moeckel	218472US0X	7547
22850	7590	08/31/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/075,460	Applicant(s) MOECKEL ET AL.	
	Examiner Richard G Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23, 25-30, 41-87 and 89-91 is/are pending in the application.
- 4a) Of the above claim(s) 12-23, 25-30 and 82-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46, 48, 49, 51-53, 55, 59-76 and 88-91 is/are rejected.
- 7) ☒ Claim(s) 47, 50, 54, 56-58, 77-81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2004 has been entered.

Applicants amendment of claims 41, 42, 46 and 49 and the addition of new claims 41-91, in the paper of 6/21/2004, is acknowledged. Claims 12-23, 25-30 and 41-91 are at issue and are present for examination.

Applicants' arguments filed on 5/20/2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicants continued comments with regard to the rejoinder of the nonelected groups are acknowledged, however these will be dealt with upon the indication of allowability of the elected claims as per MPEP 821.04.

Claims 12-23 and 25-30 and 82-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 6.

Claim Objections

Claims 47, 50, 54, 56-58,77-81 are objected to because of the following informalities:

Claims 47, 50, 54, 56-58,77-81 depend from rejected claims.

. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89-91 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action . In response to this rejection, applicants have amended the claims and argue the rejection as it applies to the newly amended claims.

Applicants argue that the currently rejected claims include a newly added "functional limitation" however, the currently rejected claims do not contain such a limitation, and thus this traversal is not found persuasive.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 41-46, 48, 49, 51-53, 55, 59-76 and 88-91 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide which comprises a mere 15 consecutive nucleotides of SEQ ID NO: 3 or is 95% identical to SEQ ID NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims as directed to SEQ ID NO: 1/2. In response to this rejection, applicants have amended the claims so as to be drawn to SEQ ID NO: 1, 2 and 4, and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection in light of the *In re Wands* factors recited.

Applicants submit that the quantity of experimentation merely involves expressing a particular polynucleotide sequence having at least 95% identity to SEQ ID NO: 1 in a corynebacteria and observing the results and that the specification provides adequate direction and guidance to do this and actually exemplifies such an assay. Applicants further submit that the nature of the invention and the prior art is such that it

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is routine to make or select such variants and the level of skill in the art and predictability high.

Applicants argument is fully acknowledged as well as applicants amendment of the claims such that the referred to genus is now drawn to SEQ ID NO: 4, instead of or in addition to SEQ ID NO:1.

Applicants argument is not found persuasive because while the specification teaches the complete amino acid sequence of SEQ ID NO:4, and protocols for modifying polynucleotide and thus amino acid sequences are well known within the art, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., having the claimed function) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the polynucleotide structure which may be modified without effecting the desired activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and

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predictable scheme for modifying any nucleic acid residue of SEQ ID NO: 1 or any amino acid residue of SEQ ID NO: 4, with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity claimed and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polynucleotides of the claimed genus.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide with the claimed structural relationship to SEQ ID NO: 1, 2, 3 or 4. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 89-91 remain rejected under 35 U.S.C. 102(a) as being anticipated by Nagawa et al., "Satochi et al." (EP 1 108 790, reference AP on IDS, Paper No. 4).

Claims 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Nair et al. (Nucleic Acids Research, Vol 21, No. 4, page 1039, 1993, reference AV on IDS, Paper No. 4).

These rejections are stated in the previous office action. In response to these rejections applicants have cancelled claim 88 and amended claims 89-91 and traverse the rejections as they apply to the newly amended claims.

Applicants submit that the rejections are moot in light of the use of "consisting of".

Applicants amendment and argument has been fully considered, however found nonpersuasive, in light of the following.

The rejected claims recite the following "An isolated polynucleotide consisting of at least 15 consecutive nucleotides of nucleotides 1-499 or 884-1775 of SEQ ID NO: 1...(claim 89)". Applicants appear to argue that the claim is drawn to a polynucleotide which "consists of" the referred to reference sequence. Applicants argument is not found persuasive because the recited claim specifically states "consisting of **at least**" which the office has interpreted as open type language, whereby the claimed

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polynucleotide must “consist of” “ **at least**” the referenced sequence, but allow for additional sequence by virtue of the reference to “at least”. This allows for the claimed polynucleotide sequence “ in addition to the reference sequence”, thus opening up the claimed genus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a horizontal line drawn through the middle of the signature.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
8/18/2004